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Patrick Fay, Esq. FAY KAPLUN & MARCIN, LLP Suite 702 150 Broadway New York, NY 10038				
EXAMINER				
SCHELL, LAURA C				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/777,545

Applicant(s)

DIMATTEO ET AL.

Examiner

LAURA C. SCHELL

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 8, 10, 11, 16, 17, 19, 22 and 24-28 is/are pending in the application.
- 4a) Of the above claim(s) 22 and 24-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 8, 10, 11, 16, 17, 19, 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 6, 8, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quinn (US 2001/0018576) in view of Igarashi et al. (US Patent No. 7,282,041). Quinn discloses the device substantially as claimed including a catheter (Figs. 41-47) comprising: a catheter tube (811) containing a first and second tube lumens in said tube (827a and 827b, respectively); a distal tip (810) connected directly to said catheter tube (Figs. 41-47), the radial dimension of said tip being substantially the same as the radial dimension of the tube adjacent said tip (Figs. 41-47 disclose the dimensions are the same); said distal tip having first and second tip lumens (859a and 859b, respectively) extending therethrough, wherein in an operative configuration, the

first and second tip lumens are connected to said first and second tube lumens of said of said catheter tube; a partition separating the first tip lumen from the second tip lumen (858); a first opening (837) fluidly connected to the first tip lumen for inflow of fluid from a body lumen into which the distal tip is inserted in a normal mode of operation and for outflow of fluid into said body lumen in a reverse mode of operation (Figs. 41-46, first opening is 837); a second opening (877) fluidly connected to the second tip lumen, the second opening being disposed distally from the first opening and separated from the first opening by a selected stagger distance for outflow of fluid from the first opening when the catheter is in the normal mode of operation and for inflow of fluid from the body lumen in a reverse mode of operation (Figs. 41-46 disclose that the second opening is 877); a contoured flow deflection element (820/876) directing in the reverse mode of operation, outflow from the first opening away from the second opening; a contoured outlet portion (873/857) of the second opening reducing an outflow velocity therefrom in the normal mode of operation. Quinn's embodiment in Figs. 41-46, however, does not disclose side walls extending away from the partition on the same side as the first opening to create a channel between the first opening and the contoured flow deflection element. Quinn, however, does disclose in various other embodiments (Figs. 9 and 10 for example) a catheter with an opening (69) and sidewalls extending away from the partition to create a channel entirely between the first opening and the contoured flow deflection element (Figs. 10 discloses that side walls 71 extend away from the partition bottom 72 between the opening and the contoured flow deflection element 57 to create a channel. Furthermore, Fig. 10 discloses that the side

walls are labeled as 71 and Fig. 9 discloses that 71 starts at the intersection of sidewalls 71 with inclined portion 69. Fig. 9 further discloses that 71 extends to the right at level height, therefore indicating that sidewalls 71 extend all the way between where 69 ends and where the bolus tip portion begins). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Quinn's embodiment in Figs. 41-47 with the side walls, as taught by Quinn in the embodiment of Figs. 9 and 10, in order to provide an inlet/outlet which helps keep the fluid flowing in the intended direction in order to prevent the fluid from spilling over the sides and contaminating the fluid that is either coming in/going out the other opening. Quinn also does not disclose that the distance between the first opening and the second opening are between 1 and 1.5 cm. Igarashi, however, discloses a similar catheter with staggered inflow and outflow openings (Fig. 24 for example) and further discloses that the distance between the inflow and outflow ports can be between 5 mm and 70 mm, which is equivalent to between 0.5 and 7 cm, which wholly encompasses the range claimed by Applicant. Therefore it would have also been obvious to one of ordinary skill in the art at the time of the invention to have modified Quinn's catheter such that the openings were spaced apart by between 1 and 1.5 cm, as this range is taught as a desirable distance by Igarashi, and furthermore, a change in size is generally recognized as being within the level of ordinary skill in the art.

In reference to claim 2, Quinn discloses that the first and second openings are disposed on opposite sides of the distal tip with respect to a longitudinal axis thereof (Figs. 41-46).

In reference to claim 3, Quinn discloses that the first and second openings have orifices extending in planes angled with respect to a longitudinal axis of the distal tip (Figs. 41-46).

In reference to claim 4, Quinn discloses that the contoured flow deflection element is adapted to direct outflow from the second opening away from the first opening in the normal mode of operation (Figs. 41-46).

In reference to claim 6, Quinn discloses that the first opening includes a longitudinally elongated first ramp portion (near 820) deflecting outflow therefrom away from a longitudinal axis of the distal tip in the reverse mode of operation (Figs. 41-46).

In reference to claim 8, Quinn discloses that the second opening includes a longitudinally elongated second ramp portion (near 878/889) deflecting outflow from the second opening away from a longitudinal axis of the distal tip in the normal mode (Figs. 41-46).

In reference to claim 10, Quinn discloses that the first and second lumens have substantially d-shaped cross sections (Figs. 41-46).

In reference to claim 11, Quinn discloses a contoured bolus (873) on said tip, including a longitudinally elongated first ramp substantially aligned with the first opening, a longitudinally elongated second ramp aligned with the second opening and an atraumatic distal tip (857).

Claims 16, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quinn (US 2001/0018576) in view of Igarashi et al. (US Patent No. 7,282,041). Quinn discloses the catheter tip substantially as claimed including a flow control tip for a catheter including a single catheter tube (Figs. 41-47, 811) containing multiple lumens (827a and 827b), comprising: an attachment portion directly connected to a distal portion of said catheter tube (attachment portion is near 858/852 for example); and a contoured bolus (810) defining at least a portion of an inlet (837) and an outlet (877/889) of the distal tip, the inlet and outlet being separated by a partition (858) so that when coupled to the catheter, the inlet is coupled to a first one of the lumens and the outlet is coupled to a second one of the lumens, and a longitudinally elongated flow deflector (near 820) directing fluids exiting the inlet in a first mode away from the outlet, wherein the contoured bolus defines a specified stagger distance between the inlet and the outlet (Figs. 41-47). Quinn's embodiment in Figs. 41-46, however, does not disclose side walls extending away from the partition on the same side as the first opening to create a channel between the first opening and the contoured flow deflection element. Quinn, however, does disclose in various other embodiments (Figs. 9 and 10 for example) a catheter with an opening (69) and sidewalls extending away from the partition to create a channel between the first opening and the contoured flow deflection element (Figs. 10 discloses that side walls 71 extend away from the partition bottom 72 between the opening and the contoured flow deflection element 57 to create a channel. Furthermore, Fig. 10 discloses that the side walls are labeled as 71 and Fig. 9 discloses that 71 starts at the intersection of sidewalls 71 with inclined portion 69. Fig. 9 further

discloses that 71 extends to the right at level height, therefore indicating that sidewalls 71 extend all the way between where 69 ends and where the bolus tip portion begins). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Quinn's embodiment in Figs. 41-47 with the side walls, as taught by Quinn in the embodiment of Figs. 9 and 10, in order to provide an inlet/outlet which helps keep the fluid flowing in the intended direction in order to prevent the fluid from spilling over the sides and contaminating the fluid that is either coming in/going out the other opening. Quinn also does not disclose that the distance between the first opening and the second opening are between 1 and 1.5 cm. Igarashi, however, discloses a similar catheter with staggered inflow and outflow openings (Fig. 24 for example) and further discloses that the distance between the inflow and outflow ports can be between 5 mm and 70 mm, which is equivalent to between 0.5 and 7 cm, which wholly encompasses the range claimed by Applicant. Therefore it would have also been obvious to one of ordinary skill in the art at the time of the invention to have modified Quinn's catheter such that the openings were spaced apart by between 1 and 1.5 cm, as this range is taught as a desirable distance by Igarashi, and furthermore, a change in size is generally recognized as being within the level of ordinary skill in the art.

In reference to claim 17, Quinn discloses that the contoured bolus further comprises a second longitudinally elongated flow deflector directing fluid exiting the outlet in a second mode away from the inlet (near 878/857).

In reference to claim 19, Quinn discloses that the flow deflector comprises a ramp disposed adjacent an inlet opening (Figs. 41-46).

Response to Arguments

Applicant's arguments with respect to claims 1-4, 6, 8, 10, 11, 16, 17, 19 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/
Examiner, Art Unit 3767
/Kevin C. Simmons/
Supervisory Patent Examiner, Art Unit 3767